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K011858

JUN 1 9 2001

BD

Indispensable to human health

# Summary of Safety and Effectiveness for InterLink® Threaded Lock Cannula

1 BD Contact person:

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Director, Regulatory Affairs
BD Medical Surgical – Mail Code 226
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2 Device Name: InterLink® Threaded Lock Cannula

3 Predicate Device(s): BD/Baxter InterLink® Blunt Cannula, Modification 510(K) K911868, Date of Decision: 06/24/91

4 Intended Uses: **(REVISED):** The Threaded Lock Cannula is one of several needleless cannula components that are part of the InterLink® IV Access System that provide for continuous and intermittent IV Therapy, Vial Access, and Blood Draws. The system allows the user to make connections to any IV line using a mating injection site with a pre-slit septum safely without chance of needle stick injury to the user or patient. InterLink® Threaded Lock Cannula are specifically designed for use with InterLink® injection sites, identified by a white alert ring around the septum. Not compatible with conventional injection sites.

5 Device Description and Comparison: **(REVISED)**

A product comparison between the modified InterLink® Threaded Lock Cannula and existing Threaded Lock Cannula is provided in the table below:

| Component/ Characteristic | Threaded Lock (existing) | Threaded Lock (modified) |
|---|---|---|
| **Cannula Body** | Polypropylene | Polypropylene |
| **Tip Shield (Cannula Stem)** | Polyethylene | Polyethylene |
| **Lubricant** | Medical Grade Silicone | Medical Grade Silicone |
| **Sterilization Process** | Radiation | Radiation |

The Threaded Lock Cannulae are equivalent in product function, design, and manufacturing process with the only difference being the addition of 'micro' helical thread molded internally between the existing double start, 0.100 nominal pitch luer thread. The 'micro' thread provides additional surface to surface contact with the mating threads on the injection site body and enhances the security of the connection.

**6** Equivalence determination:

The BD 'modified' InterLink® Threaded Lock Cannula is substantially equivalent in product function and intended use to the existing 'unmodified' predicate device InterLink® Threaded Lock Cannula, and exhibits the following similarities as detailed in the table below:

| | **Threaded Lock Cannula (modified)** | **Threaded Lock Cannula (existing)** |
|---|---|---|
| **Intended Use** | Used for needleless access to IV Sites connected to an injection site for continuous and intermittent IV Therapy. | Used for needleless access to IV Sites connected to an injection site for continuous and intermittent IV Therapy. |
| **Incorporates Same Basic Design** | Yes | Yes |
| **Utilizes Same Operating Principle** | Yes, lubricated and shielded cannula with standard female luer fitting hub. Injection site threads are enhanced with addition of 'micro' thread for added security for connection to mating injection site body. | Lubricated and shielded cannula with standard female luer fitting hub. Standard threads provide for attachment to mating injection site body. |
| **Incorporates Same Material** | Yes - Polypropylene Resin | Yes - Polypropylene Resin |
| **Sterility** | Sterile 10 -6 SAL | Sterile 10 -6 SAL |
| **Sterilization Process** | Gamma Radiation | Gamma Radiation |
| **Toxicity** | Non-Toxic | Non-Toxic |
| **Pyrogenicity** | Non-pyrogenic | Non-pyrogenic |
| **Product Size** | .915" x .500" Diameter | .915" x .500" Diameter |

In summary the 'modified' InterLink® Threaded Lock Cannula described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2001

Mr. Gregory W. Morgan
Head of Regulatory Compliance
BD Medical Surgical
1 Becton Drive MC 226
Franklin Lakes, New Jersey 07417

Re: K011858
Trade/Device Name: Interlink Threaded Lock Cannula
Regulation Number: 880.5440
Regulatory Class: II
Product Code: FPA and FMI
Dated: June 13, 2001
Received: June 14, 2001

Dear Mr. Morgan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Attachment 5**

## Indications for Use Statement

510(k) Number: not known at this time

Device Name: InterLink® Threaded Lock Cannula

Indications for Use: The Threaded Lock Cannula is one of several needleless cannula components that are part of the InterLink® IV Access System that provide for continuous and intermittent IV Therapy, Vial Access, and Blood Draws. The system allows the user to make connections to any IV line using a mating injection site with a pre-slit septum safely without chance of needle stick injury to the user or patient. InterLink® Threaded Lock Cannula are specifically designed for use with InterLink® injection sites, identified by a white alert ring around the septum. Not compatible with conventional injection sites.

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011858